IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicant(s): B. Lauren Charous Examiner: Unassigned

Serial No: To be assigned Art Unit: Unassigned

Filed: Herewith Docket: 15078Z

For: A METHOD FOR TREATING

Dated: February 13, 2004

INFLAMMATORY BOWEL DISEASE

Commissioner for Patents Alexandria, VA 22313-1450

INFORMATION DISCLOSURE STATEMENT

Sir:

In accordance with 37 C.F.R. §§ 1.97 and 1.98, it is requested that the following disclosures, which are also listed on the attached Form PTO-1449, be made of record in the above-identified case.

- 1. U.S. Patent No. 4,181,725 to Voorhees, et al., issued January 1, 1980;
- 2. Barnes, Peter J., "Asthma Therapy with Aerosols: Clinical Relevance for the Next Decade", <u>Journal of Aerosol Medicine</u>, Vol. 9, No. 1, 1996, pp. 131-141;
- 3. Busse, William W., et al., "Treatment Regimen and Side Effects of Treatment Measures", Am. J. Respir. Crit. Care Med., Vol. 149, pp. S44-S50, 1994;

CERTIFICATE OF MAILING BY "EXPRESS MAIL"

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I hereby certify that this correspondence is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 C.F.R. §1.10 on the date indicated above and is addressed to the Commissioner of Patents and Trademarks, Alexandria, VA 22313-1450.

Dated: February 13, 2004

- 4. Charous, Lauren B., "Open study of hydroxychloroquine in the treatment of severe symptomatic or corticosteroid-dependent asthma", <u>Annals. of Allergy</u>, Vol. 65, July, 1990, pp. 53-58;
- 5. Charous, Lauren B., et al., "Hydroxychloroquine improves airflow and lowers circulating IgE levels in subjects with moderate symptomatic asthma", <u>J. Allergy Clin. Immunol.</u>, Vol. 102, No. 2, 1998, pp. 198-203;
- 6. Charous, Lauren B., "Effectiveness of Long-Term Treatment of Severe Asthma with Hydroxychloroquine (HCQ)", <u>Annals. of the New York Academy of Sciences</u>, Vol. 629, pp. 432-433;
- 7. Charous, Lauren B., et al., "Double-blind Trial of Hydroxychloroquine (HCQ) as Anti Allergic Anti-Asthmatic Therapy", <u>J. Allergy Clin. Immunol.</u>, January 1997;
- 8. Charous, Lauren B., "Long-Term Treatment of Severe Asthma with Hydroxychloroquine", <u>Annals of Allergy</u>, Vol. 68, No. 1, p. 80, 1992;
- 9. Charous, Lauren B., "Double-blind Trial of Hydroxychloroquine (HCQ) As Anti-Allergic Anti-Asthmatic Therapy", J. Allergy Clin. Immunol., January 1997, p. S268;
- 10. Cockcroft, D.W., "Therapy for airway inflammation in asthma", <u>J. Allergy Clin. Immunol.</u>, May 1991, Vol. 87, No. 5. pp. 914-919;
- 11. Fox, Robert I., et al., "Treatment of Primary Sjogren's Syndrome with Hydroxychloroquine", <u>The American Journal of Medicine</u>, Vol. 85, 1998, p. 62-67;
- 12. Goldstein, Jay A., "Hydroxychloroquine for Asthma", <u>Am. Rev. Res.</u> <u>Diseases</u>, 128(6):1100-1101;
- 13. Landwehr, Lawrence P., et al., "Management of Steroid-Resistant Asthma", Clin. Immunother., 4(2) 1995, pp. 124-137;
- 14. Ledford, Dennis K., "Alternative Treatments for Severe, Chronic Asthma", Allergy Proc., January-February 1993, Vol. 14, No. 1, pp. 23-30;
- 15. Ledford, Dennis K., "Treatment of Steroid-Resistant Asthma", Immunology and Allergy Clinics of North America, Vol. 16, No. 4, November 1996, pp. 777-796;
- 16. Moss, Richard B., "Alternative Pharmacotherapies for Steroid-Dependent Asthma", Chest, Vol. 107, No. 3, March 1995, pp. 817-825;

- 17. Ornstein, Matthew H., et al., "The Anti-Inflammatory and Antiviral Effects of Hydroxy-Chloroquine (HCQ) in 2 Patients with Aids and Active Inflammatory Arthritis", Arthritis & Rheumatism, Vol. 38, No. 9, p. S198;
- 18. Roberts, J.A., et al., "Effect of Hydroxychloroquine in Chronic Steroid Dependent Asthma", J. Allergy Clin. Immune, 1986, Vol. 77, No. 1, Part 2, p. 151;
- 19. Roberts, J.A., et al., "Hydroxychloroquine in Steroid Dependent Asthma", Pulmonary Pharmacology, 1998, p. 59-61;
- 20. Seggey, J.S., et al., "Inhibition of IL-4-Driven IgE Synthesis by Peripheral Blood Lymphocytes (PBL) in vitro with Hydroxychloroquine (HCQ)", <u>Allergic Disease IgE</u>, No. 343, p. 62A;
- 21. Sherman, et al., "Short-Term Effects of Hydroxychloroquine (HCQ) on IgE Levels and Obstructive Airways Disease", <u>J. Allergy Clin. Immunol.</u>, January 1992, No. 567, p. 286; and
- 22. Sorkness, Christine, et al., "Alternatives to Corticosteroids in the Treatment of Asthma", <u>Immunology and Allergy Clinics of North America</u>, Vol. 13, No. 4, November 1993, p. 917-938.

Pursuant to 37 C.F.R. §1.98(d), copies of the above listed references are not provided, as references 1-22 were previously submitted to the Examiner and in connection with parent case, U.S. Serial Number 10/293,769 filed on November 12, 2000.

Inasmuch as this Information Disclosure Statement is being filed prior to the issuance of any action on the merits, no fee or certification is due.

Respectfully submitted

Mark J. Coher

Registration No.: 32,211

Scully, Scott, Murphy & Presser 400 Garden City Plaza Garden City, New York 11530 (516) 742-4343 MJC:lf

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	AM	Barnes, Peter J., "Asthma Therapy with Aerosols: Clinical Relevance for the Next Decade", <u>Journal of Aerosol Medicine</u> , Vol. 9, No. 1, 1996, pp. 131-141.							
	AN	Busse, William W., et al., "Treatment Regimen and Side Effects of Treatment Measures", Am. J. Respir. Crit. Care Med., Vol. 149, pp. S44-S50, 1994.							
	AO	Charous, Lauren B., "Open study of hydroxychloroquine in the treatment of severe symptomatic or corticosteroid-dependent asthma", Annals. of Allergy, Vol. 65, July, 1990, pp. 53-58.							
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) 	AS	Charous, Lauren B., et al., "Double-blind Trial of Hydroxychloroquine (HCQ) as Anti Allergic Anti-Asthmatic Therapy", <u>J. Allergy Clin. Immunol.</u> , January 1997.							
	ΑТ	Charous, Lauren B., "Long-Term Treatment of Severe Asthma with Hydroxychloroquine", <u>Annals of Allergy</u> , Vol. 68, No. 1, p. 80, 1992.							
	AU	Charous, Lauren B., "Do Clin. Immunol., January		lydroxychloroquine (HCQ) As An	ti-Allergic Aı	nti-Asthmatic T	herapy", J. A	llergy	
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	AN	Sherman, et al., "Short-Term Effects of Hydroxychloroquine (HCQ) on IgE Levels and Obstructive Airways Disease", J. Allergy Clin. Immunol., January 1992, No. 567, p. 286.								
	AO	Sorkness, Christine, et al., "Alternatives to Corticosteroids in the Treatment of Asthma", <u>Immunology and Allergy Clinics of North America</u> , Vol. 13, No. 4, November 1993, p. 917-938.								
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